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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,210	10/16/2001	Shian-Jiun Shih	A2922AUS	2753

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,210	Applicant(s) SHIH ET AL.	
	Examiner Janet L. Epps-Ford	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-13,18,22-24 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-13,18,22-24,26-31 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-12-05 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 102

3. The rejection of Claims 1, 3 to 5, 22, 26 and 28 under 35 U.S.C. 102(a) as being anticipated by Crespo (WO 97/33975, wherein the English version is US 6,248,588), is withdrawn in response to Applicant's amendment.

Claim Rejections - 35 USC § 103

4. Claims 1, 7 to 13, 22 to 24, 26 and 29 to 31 remain rejected and new claim 34 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Crespo in view of Engler et al. (US 2003/021 1598); and claims 1, 3-5, 7-13, 18, 22-24, and 26-31 remain rejected under 35 USC 103(a) as being unpatentable over Crespo in view of Engler et al. (US 2003/021 1598), and further in view of Rolland et al. and Sene, for the reasons of record.

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5. Applicants traverse the instant rejection on the grounds that the present rejection does not provide 1) a suggestion or motivation to combine the references, or 2) a reasonable expectation that the combination will be successful. According to Applicants steps 1) and 2) must be found in the prior art. Applicant submits that the present rejection has not satisfied any of these requirements. Specifically, Applicants argue that Crespo does not disclose compositions useful for preserving adenoviral particles or vectors at temperatures above freezing and there is no evidence to suggest that the compositions of Crespo would be effective at these temperatures.

6. Additionally, Applicants traversed the rejection of claims 1, 3-5, 7-13, 18, 22-24, and 26-31 on the grounds that the combination of Crespo and Engler et al. are non-obvious, and that Rolland et al. and Sene provide no basis to overcome these deficiencies.

7. Contrary to Applicant's assertions, the compositions of Crespo et al. teach that their disclosed medium, allow both freezing and thawing of biological material under conditions of high viability, and the temperature range for freezing of between -200 to -4 degrees Celsius is well below the temperature range recited in the instant claims. Although, Crespo et al. does not specifically recite that the medium is effective to stabilize the virus at temperatures from about 4°C to about 20°C, the reference does teach that the medium is sufficient to allow thawing of biological material under conditions of high viability, absent evidence to the contrary, temperatures of from about 4°C to about 20°C represent conditions of thawing as set forth by Crespo et al.

Furthermore, according to Applicants there is no suggestion or motivation to combine the references and the reasonable expectation that the combination will be successful. As stated previously the disclosure of Crespo et al. (see Col. 8, lines 55-60 or page 14 of the WO document) discloses that the adenoviral vectors can be admixed with any of the disclosed buffered solutions for their preservation, moreover, Crespo as a whole teaches that the solutions can be used for storage, thawing and subsequently for a direct injection of adenoviral vectors in a subject. Additionally, Engler et al. teaches that pharmaceutical buffers comprising Tris-HCl (containing 1-3 mM $MgCl_2$) is a suitable buffer for adenoviral vectors. Therefore, contrary to Applicant's assertions, and absent any evidence of record, it would have been obvious to the ordinary skilled artisan to employ a pharmaceutical buffer comprising a salt such as Tris-HCl in (which contains that is disclosed as useful for adenoviral vectors) combination with the solutions disclosed by Crespo et al., since Crespo et al. teach that a saline solution can be used in their solutions for preserving adenoviral vectors as long as the saline solution contained the required salts, and/or $MgCl_2$. (Applicants have not addressed this point raised by the examiner in the Office Action mailed 3-09-05, page 6). Absent evidence to the contrary, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in employing the Tris-HCl/NaCl/ $MgCl_2$ /HSA based solution (produced by the combination of Crespo and Engler et al.) in preserving and storing adenoviral vectors because each of the ingredients employed in the solution is expected to help stabilize and/or enhance the intended function of the adenoviral vectors, as taught by the combination of the references as a whole.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3-5, 7-13, 18, 22-24, 26-31, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 recites "about 0.1% to about 25% human serum albumin (HSA)." However, this phrase is indefinite since it is unclear if the phrase is intended to encompass, for example, the concentration of HSA in the composition as a whole, the weight of HSA in the composition, the individual concentration of an HSA solution added to the composition, etc. The metes and bounds of this phrase are vague and indefinite, and the skilled artisan would not be able to ascertain the full scope of the claimed invention and therefore would not understand how to avoid infringement. It is noted that original claim 2 recited "wherein the concentration of HSA is from about 0.01% to about 25% (w/v)."


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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford
Primary Examiner
Art Unit 1633

JLE